21 June 2012
EMA/CHMP/417185/2012

Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Zoledronic acid Mylan

Zoledronic acid

On 21 June 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zoledronic acid Mylan 4 mg/5 ml concentrate for solution for infusion intended for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone, and for the treatment of adult patients with tumour-induced hypercalcaemia (TIH).

The applicant for this medicinal product is Mylan S.A.S.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Zoledronic acid Mylan is zoledronic acid (as monohydrate), a bisphosphonate (M05BA08). Zoledronic acid stops the action of the osteoclasts, the cells in the body that are involved in breaking down the bone tissue. This leads to less bone loss. The reduction of bone loss helps to make bones less likely to break, which is useful in preventing fractures in cancer patients with bone metastases. Patients with tumours can have high levels of calcium in their blood, released from the bones. By preventing the breakdown of bones, zoledronic acid also helps to reduce the amount of calcium released into the blood.

Zoledronic acid Mylan is a generic of Zometa, which has been authorised in the EU since 20 March 2001. Studies have demonstrated the satisfactory quality of Zoledronic acid Mylan. This product is administered intravenously and is 100% bioavailable; therefore, a bioequivalence study versus the reference product Zometa was not required. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Zoledronic acid Mylan will be implemented as part of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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The approved indications are:

- “Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone.
- The treatment of adult patients with tumour-induced hypercalcaemia (TIH)”.

Zoledronic acid Mylan must only be prescribed and administered to patients by healthcare professionals experienced in the administration of intravenous biphosphonates.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Zoledronic acid Mylan and therefore recommends the granting of the marketing authorisation.